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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

IBRAHIM et al — Atty. Ref.: 2590-35

Serial No. 10/049,379 — TC/A.U.: 1615

Filed: February 12, 2002 — Examiner: Robert M. Joynes

For: PHARMACEUTICALLY STABLE OXALIPLATINUM PREPARATION FOR PARENTERAL ADMINISTRATION

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April 11, 2005

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

In response to the Examiner's Answer of February 11, 2005, Applicant submits this Reply Brief.

At the outset, it is noted with appreciation that the Examiner has withdrawn the rejection of claims 1-11 and 15-17 based upon the Ibrahim reference (U.S. Patent 5,716,988) in view of the Blackshear reference (U.S. Patent 4,439,181).

The following comments are directed to the Examiner's continued rejection of claims 1-11 and 15-17 as being obvious over Ibrahim (U.S. Patent 5,716,988) in view of Schlipalius (U.S. Patent 5,897,871). Applicant respectfully requests the reversal of this rejection.

On page 4 of the Examiner's Answer, the Examiner contends that Ibrahim does not expressly teach the exact concentration for the oxaliplatinum nor does the reference teach other solvents for the solution. Although the Examiner is correct with respect to the lack of any teaching of the claimed solvents, the Examiner's concentration statement is not correct because

Ibrahim does teach a concentration -- from 1 to 5 mg/ml, and preferably 2 mg/ml -- both of which are significantly different than the claimed concentration of at least 7 mg/ml. Correctly stated, Ibrahim does not teach the claimed concentration or the claimed solvent. Stated another way, the Examiner's incorrect and over generalized concentration assertion renders the obviousness rejection defective.

The following two contentions in the Examiner's Answer are also erroneous, and they underscore the erroneous obviousness rejection. First, in the first paragraph on page 5 of the Examiner's Answer, the Examiner contends that the Applicant has not provided any evidence that the claimed concentration of greater than 7 mg/ml is "critical." (See the first sentence on page 5.) Second, in conflict with the Examiner's own statements on page 4 of the Examiner's Answer that Ibahim does not teach an exact concentration, the Examiner now contends on page 5 of the Answer that the Ibrahim concentration is "close" to the claimed concentration. (See the next to last sentence in the first full paragraph on page 5.) Both of these contentions are incorrect as explained below.

Contrary to the Examiner's first position, the Applicant has stated that the concentration range of greater than 7 mg/ml is critical to the claimed invention. See, e.g., the Applicant's specification beginning with the paragraph at the bottom of page 1 and ending with the paragraph at the bottom of page 3. This disclosure discusses the problems of the prior art preparation compared to the critical and "surprisingly found" concentration of the claimed invention.

Contrary to the Examiner's second position, the concentration range of Ibrahim is **not** close to the claimed concentration range. Indeed, the minimum claimed concentration is anywhere from 40% to 600% higher than the range taught in Ibrahim. More specifically,

Ibrahim teaches a concentration range of from 1 to 5 mg/ml compared to the claimed range of greater than 7 mg/ml. Further, Ibrahim teaches a preferred range of 2 mg/ml. Indeed, the minimum claimed amount of 7 mg/ml is more than 300% higher than Ibrahim's preferred range. This is significant -- especially in the medical field -- and demonstrates the non-obviousness of the claimed invention.

Near the bottom of page 6 of the Examiner's Answer, the Examiner contends that the two pieces of prior art clearly teach and suggest an oxaliplatinum preparation that provides for stability for 3 to 5 years at room temperature or at the temperature of a refrigerator. However, the Examiner does not accurately state that the prior art oxaliplatinum preparation is completely different than the claimed preparation, e.g., different concentration, different solvent, etc. The Examiner's Answer does not appreciate or properly recognize that a preparation in a much higher concentration is quite beneficial in the health care field because it significantly reduces the pharmaceutical preparation volumes and administrations. See, for example, the bottom of page 2 of the patent application.

Stated another way, the rejection has not correctly set forth all of the beneficial properties of the claimed invention -- which are not present in the prior art. Indeed, a 300% increase in the claimed concentration over the preferred concentration of the primary reference would correspondingly lead to at least a multi-fold benefit in the handling and administration of the pharmaceutical preparation. This is incredibly significant in the health care field -- and the rejection and Examiner's Answer nowhere mentions the significance of this development of the claimed invention. This invention can be used with great success in the prefilled syringe field.

On page 8 of the Examiner's Answer, it finally acknowledges that Ibrahim does not expressly teach the claimed concentration and the claimed solvents. Nevertheless, the Answer

contends that Schlipalius remedies this deficiency of Ibrahim by teaching agents administered by injection or infusion, wherein the active agents are used in solution with glycerol. As stated previously, this is an improper use of hindsight using the subject application as a guide to improperly combine Ibrahim and Schlipalius. Neither Ibrahim nor Schlipalius teach or suggest the claimed critical concentration range of greater than 7 mg/ml in conjunction with a specific solvent to yield a stable pharmaceutical preparation.

This has been confirmed in U.S. Patent Application Serial No. 10/450,260, where the Examiner in that case unequivocally stated in the Office Action of February 11, 2005:

> The [Ibrahim] reference fails to teach or suggest that higher concentrations may be employed and thus, it is not seen that one of ordinary skill in the art would have been motivated to modify the preparation disclosed therein to contain "at least 7 mg/ml" as required by the present claims.

The Applicant is in complete agreement with this USPTO statement, and the USPTO statement fully supports the reversal of the remaining rejection in this appeal.

CONCLUSION

It is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

Respectfully submitted,

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